1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
Product Identity: Tetagam® P
Alternate Names: Human tetanus immunoglobulin

1.2. Relevant identified uses of the substance or mixture and uses advised against
Intended use: See Technical Data Sheet.
Application Method: See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet
Company Name: CSL Behring L.L.C.
1020 First Avenue
PO Box 61501
King of Prussia, PA

Emergency
24 hour Emergency Telephone No.: Emergency Response: (800) 424-9300
Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring L.L.C.
(610) 878-4000

2. Hazard identification of the product

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008
No applicable CLP categories.
Classification according to 67/548/EEC or 1999/45/EC.
No applicable DPD categories.

2.2. Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.
According to Regulation (EC) No 1272/2008
[Prevention]:
No CLP prevention statements
[Response]:
No CLP response statements
[Storage]:
No CLP storage statements
[Disposal]:
No CLP disposal statements
See Technical disposal Sheet.

2.3. Other hazards
This product contains no PBT/vPvB chemicals.

### 3. Composition/information on ingredients

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

**Non-Hazardous Ingredients**
- **Material:** Medicinal product derived from human plasma.
- **Active ingredient:** Human tetanus immunoglobulin (non hazardous component).
- **Other components:** Aminoacetic acid, sodium chloride, (non hazardous components).

**Packaging units:** Pack with 1, 50 ampoules, each of 1 ml, or pack with 1, 10 pre-filled syringes of 1 ml, pack with 1 pre-filled syringe of 2 ml solution (ready-for-use) for intramuscular administration.

### 4. First aid measures

#### 4.1. Description of first aid measures

**General**
- In all cases of doubt, or when symptoms persist, seek medical attention.
- Never give anything by mouth to an unconscious person.

**Inhalation**
- Remove to fresh air.

**Eye**
- Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

**Skin**
- Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

**Ingestion**
- Drink water. Obtain medical attention if feeling ill.

#### 4.2. Most important symptoms and effects, both acute and delayed

**Overview**
- No specific symptom data available.

### 5. Fire-fighting measures

#### 5.1. Extinguishing media
- As appropriate for surrounding fire

#### 5.2. Special hazards arising from the substance or mixture
- Hazardous decomposition: No hazardous decomposition data available.

#### 5.3. Advice for fire-fighters
- None

**ERG Guide No.**
- ****
6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions
Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up
Collect/absorb spilled material and dispose of properly.

7. Handling and storage

7.1. Precautions for safe handling
General precautions for handling of pharmaceuticals are to be considered. Protect from light when handling.

7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage.
Storage and transportation temperatures should not fall below 2C and not exceed 8C.
Incompatible materials: No data available.
Keep container closed tightly.
Store locked up or accessible to authorized persons or their representatives only.

7.3. Specific end use(s)
No data available.

8. Exposure controls and personal protection

8.1. Control parameters
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

8.2. Exposure controls
Respiratory Not Applicable
Eyes Not Applicable
Skin Not Applicable
Engineering Controls Provide adequate ventilation
Other Work Practices Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

9. Physical and chemical properties

Appearance Colorless to Pale-Yellow Up to Light Brown Liquid
Odor
Odor threshold
pH
Melting point / freezing point
Initial boiling point and boiling range
Flash Point
Evaporation rate (Ether = 1)
Flammability (solid, gas)
Upper/lower flammability or explosive limits
Vapor pressure (Pa)
Vapor Density
Specific Gravity
Solubility in Water
Partition coefficient n-octanol/water (Log Kow)
Auto-ignition temperature
Decomposition temperature
Viscosity (cSt)
Molecular Weight
9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity
Hazardous Polymerization will not occur.

10.2. Chemical stability
Stable under normal circumstances.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
Storage and transportation temperatures should not fall below 2C and not exceed 8C.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No hazardous decomposition data available.

11. Toxicological information

Acute toxicity
All product constituents are considered to be nonhazardous. Tetagam® P is manufactured according to the same procedure as Beriglobin® P a human normal immunoglobulin. Therefore reference is made to toxicological studies performed with Beriglobin® P. The product is intended for intramuscular application only, therefore no oral, dermal or inhalation toxicity studies have been performed.

Single dose toxicity studies:
Acute toxicity studies were performed in rodents (mice, rats) with single i.m. injection. Mice were administered doses up to 8 g/kg and rats doses up to 1.6 g/kg b.w.. In a study using prefilled syringes rats were administered with 100 µL/animal intramuscularly. No relevant toxic findings were observed in these studies.

Local tolerance:
Local tolerance studies were performed in rabbits and rats with single i.m. injections. Rabbits were administered a dose of 0.5 mL (80 mg/rabbit) and rats were injected a dose of 100 µL/animal i.m., respectively. The substance was regarded as local tolerable after i.m. injection.

Safety Pharmacology:
Dogs were injected i.m. at a maximal dose of 480 mg/kg (3 mL/kg) b.w. No relevant adverse effect was observed. There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

12. Ecological information

12.1. Toxicity
No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above
the GHS cut off percentage.

12.2. Persistence and degradability
There is no data available on the preparation itself.

12.3. Bioaccumulative potential
Not Measured

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects
No data available.

13. Disposal considerations

13.1. Waste treatment methods
Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

<table>
<thead>
<tr>
<th></th>
<th>DOT (Domestic Surface Transportation)</th>
<th>IMO / IMDG (Ocean Transportation)</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1 UN number</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
<tr>
<td>14.2 UN proper shipping name</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
<tr>
<td>14.3 Transport hazard class(es)</td>
<td>DOT Hazard Class: Not Applicable</td>
<td>IMDG: Not Applicable</td>
<td>Air class: Not Applicable</td>
</tr>
<tr>
<td>14.4 Packing group</td>
<td>Not Applicable</td>
<td>Sub Class: Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>14.5 Environmental hazards</td>
<td>IMDG Marine Pollutant: No</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>14.6 Special precautions for user</td>
<td>No further information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Legislation


National Legislation
None noted.

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

Not Applicable

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

The information contained herein is based upon data considered true and accurate. CSL Behring makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

End of Document